DEVELOPING LAW ON PROFESSIONAL STANDARDS AND PEER REVIEW IN QUALITY ASSESSMENT ACTIVITIES

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INTRODUCTION

This paper describes the expanding role of professional standards and peer review activities in health-care quality assessment initiatives. It also describes how some traditional and some new quality assessment activities that involve professional and peer review are either building on or in conflict with existing legal processes and public policy. For purposes of this discussion, a "peer" will be defined as a professional equal and "peer review" as professional equals setting standards for and scrutinizing each others work: medical doctors reviewing medical doctors, nurses reviewing nurses, etc. "Professional review" will refer to inter-profession review, such as medical doctors reviewing nursing standards.

Areas of law examined include licensure, hospital and professional liability (malpractice) law, antitrust and insurance law. Activities examined include:

- standard-setting for health professionals' licensure and discipline by the states;
- professional liability (malpractice) standard-setting for practitioners and for insurance reviewers;

- enforcement of certification and accreditation standards set by voluntary agencies;
- standard-setting by and for hospitals, particularly for employee and medical staff credentialing, privileges, and quality review functions; and
- standard-setting for peer reviewers and other "quality" reviewers in state and Federal health benefits programs (e.g., Medicare).

Each of these activities is discussed in the context of policies that can promote or restrain a variety of professional initiatives: voluntary intra-profession standard setting, peer review and disciplinary activities, inter-profession review and comment on "quality of care" standards, and programs to increase the information on quality indicators that is available to consumers.

Before describing each type of review activity and its legal environment, however, several prefatory observations about the current role of professional and peer review in quality assessment initiatives are offered. Then a brief, but essential, discussion of some key facets of the American legal system is included to set the policy framework for the paper and to demonstrate why there are "crises" in some areas of health law, particularly malpractice and antitrust.

THE ROLE OF PROFESSIONAL AND PEER REVIEW IN QUALITY ASSESSMENT INITIATIVES

Professional and peer review activities play two key roles in health care quality assessment. First, professional associations set voluntary standards for evaluating members' conduct and practices. Second, individual professionals play a central role in measuring other providers' compliance with both public (and mandatory) and private (and voluntary) standards of practice.

The professional standard-setting activity is best illustrated by accreditation and certification activities of organizations like the American Medical Association (AMA), the American College of Surgeons (ACS) and other specialty societies that work individually and collaboratively through organizations such as the American Board of Medical Specialties (ABMS). Institutional accreditation involves the medical groups and other national organizations like the American Hospital Association (AHA) joining forces to form entities like the Joint Commission on Accreditation of

Health Care Organizations (JCAHO, formerly Joint Commission on Accreditation of Hosptials).

These activities that certify individuals and accredit institutions are important because such voluntary standards and evaluation activities not only have a direct impact on quality assessment, but they heavily influence mandatory quality assessment and quality assurance programs (e.g., influence of JCAHO standards on Medicare's Conditions of Participation for Hospitals). In addition, the voluntary activities of individuals and organizations can have a pivotal effect in litigation that involves quality of care judgments. For example, though many people may not think of it as such, professional liability (malpractice) litigation is essentially a peer review activity. A malpractice case cannot be tried without peer testimony as to the standard of care applicable and peer judgments about whether the defendant met that standard.

Given the growth of consumer activism in this country and the introduction of new techniques to attribute specific patient outcomes to specific medical interventions [1], such peer standard-setting and review initiatives should be expected to increase in number and in importance. Cost containment programs should provide added impetus, though they may change the traditional alignment of the parties at interest (e.g., the nature of the physician-patient relationship). Kathleen Lohr has probably best described the role of professional peer review with new forms of health care delivery in her "Commentary: Professional Peer Review in a 'Competitive' Medical Market:

> very considerable incentives for intensive, internal utilization review reside with the provider networks; presumably, organized peer review entities will not have much role in this activity in the future. Conversely, very considerable incentives for close monitoring of quality of care reside with patients and purchasers, as they worry about what they are getting for their money and about possible threats that underprovision of services poses for quality of care and patient outcomes. [2]

BACKGROUND ON THE U.S. LEGAL SYSTEM

The sections on licensure, malpractice, antitrust and insurance (i.e., Medicare) law that follow describe public policies that are relevant to a study of the professions' role(s) in generating quality of care information in one or more of four ways:

1. The law may have an impact on the type of expert assessment of care that can take place. For example, the discussion of malpractice law shows that physicians and other practitioners know that the quality of their work can only be evaluated in court by a member

of their own profession who shares certain professional characteristics. Practitioners with fewer skills and less expertise know that they cannot be held to standards of care developed by and applied to more highly credentialed professionals, even though the latters' standards may promote a higher quality of care for consumers.[3]

A second example where the law has an impact on expert standard-setting and regulation of practice is in the antitrust (i.e., restraint of trade) area. Despite the First Amendment (i.e., "free speech") right of an individual practitioner to comment on the acceptability of the patient care practices of another practitioner or profession, the courts are setting very stringent controls on steps that can be taken by a professional organization to restrain a practitioner's activities. Several types of cases that involve antitrust challenges to intra- and inter-profession review activities are described.

2. The law may validate or invalidate specific "quality" indicators or assessment methods being developed by health care professionals. An example of such "judicial validation" would be a court's decision about the admissibility of a formal "technology

assessment," either as a supplement to or in lieu of expert opinion testimony about the appropriate standard of practice in a malpractice case. As experts in formal technology assessment demonstrate that some standards of practice, i.e,. widely accepted clinical practices, are not beneficial or are actually harmful [4], the courts will have to determine whether and how to change the rules of evidence in malpractice litigation to bring this expert opinion into judicial decision making. [5]

3. The law may direct that consumer, not expert, expectations will be the measure of whether a professional's conduct was appropriate. For example, the evolving legal standards for determining whether a patient's consent was truly "informed" show that consumer, not practitioner, expectations are increasingly the yardstick for measuring the adequacy of the information provided to a patient. [6] A similar trend is emerging in health insurance and antitrust law; services that consumers want are being supported by the courts over the objections of insurers and providers who believe that such services are ineffective, unnecessary or dangerous. [7] [8]

4. The law may have an impact on the availability to consumers of information on quality indicators. The most obvious example of this is the enactment of state statutes that shield the records of hospital peer review and disciplinary committees from public disclosure. [9]

Sources of Law

The legal doctrines and trends described above have been--and will be--shaped by two types of lawmaking. The first source of law is the judges who shape each state's "common law" through decisions made in individual cases and approved by a state's higher appellate courts. The second source of law is legislation, both state and Federal, that creates statutory rules.

As a practical matter, prevailing law on a subject is frequently derived from both sources, from statutory directives that have needed further definition in the courts. In reviewing the cases included in this paper, it is important to remember that the development of law in any area usually proceeds one case at a time and is highly dependent on the facts of that individual case, the resources of the litigants, and the ability of the judge or jury to sort out and balance competing interests.

Limits of Adjucation

Three further observations about more global aspects of American jurisprudence are necessary before proceeding. First, there are limits to what the courts can handle. These limits are set in part by two important procedural ideas. The first is that U.S. law is based on a "notice" system. Both the criminal and civil law are grounded in the belief that citizens should be informed in advance about what is and what is not acceptable behavior. The state and Federal codes of law are written down to put people on notice about what they may and may not do. In addition, court decisions interpreting these codes are written and widely disseminated--even in the popular media--to provide further notice about the rules of conduct.

The viability of a "notice" system of governance and adjudication is extremely dependent on clear thinking and instruction by legislators and by judges. When the rules are not clear, even people acting in good faith cannot know in advance of acting whether their behavior will be deemed appropriate.

The second limitation is the notion that the effectiveness of the courts is dependent on society limiting the type of dispute presented for adjudication.

Most problems of every day life simply are not adjudicable because they lack specific decision rules and require "the exercise of unlimited discretion on the part of the decisionmaker":

> When asked, cajoled, and finally forced to try to solve unadjudicable problems, courts will inevitably respond in the only manner possible--they will begin exercising managerial authority and the discretion that goes with it. Attempts will be made to disguise the substitution, to preserve appearances, but the process which evolves should (and no doubt eventually will) be recognized for what it is--not adjudication, but an elaborate, expensive masquerade. [10]

The current crises in malpractice and antitrust health law illustrate what can happen when the law is in transition from one set of standards to another (i.e., presenting a "notice" problem) and when the courts are asked to answer open-ended questions with inadequate legislative guidance (i.e., "How should physicians practice medicine?"). Situations described in this paper show that several multi-million dollar appeals all the way to the U.S. Supreme Court can be required to find out precisely what the rules of conduct are. When this happens, the "notice" system has broken down, the courts are probably beyond their limits, and legislative intervention to clarify the rules is essential.

Judicial Bias

The second global observation about U.S. jurisprudence that is relevant here relates to the fundamental philosophical orientation of the U.S. judicial system. The American system of law has a strong bias toward protecting individual liberties. [11] Both the substance and process of law, including the civil law, seek to assure that the individual citizen gets fair consideration no matter how powerful his or her opponent. This judicial bias is strongly reinforced by the attorney ethic: an attorney has an almost unqualified obligation to pursue his client's goal and welfare.

This attorney work ethic, particularly in the context of a judicial bias that protects the individual, is a subtle and important consideration in this paper. Note that, at least until recently, the attorney ethic and the physician ethic were identical--do your utmost to take care of your individual client (and the public interest will thereby be well served). Now that the medical ethic--and health care providers generally--are being forced to factor in competing social "goods" when making some individual care decisions, the medical and legal ethics are on a collision course.

One example of this collision course is the growing litigation over what constitutes "rights" versus "privileges" for health care consumers and for practitioners. For example, a state legislature may intend to give an individual a conditional "privilege" to practice medicine when it confers a license, but a court may view the medical license as a property "right," making it much more difficult for the state to revoke the license. There are also growing numbers of cases where a legislature and a court have differed on the subject of a consumer's health care "rights," most notably with highly visible life-critical needs like organ transplantation. It appears that many more courts may be bending to the consumer perspective championed by the legal ethic in determining which services are "medically necessary," regardless of providers' or insurers' arguments to the contrary. [12]

Since quality of care judgments are likely to continue to be more absolute to the individual consumer or practitioner and more relative to guardians of the larger social welfare, it is clear that controversy related to quality assessment will increase. As in many other areas of American life, the courts will be asked to strike ever tougher balances between individual demands and collective needs.

The only way that the courts can respond credibly to these challenges is if the legislatures address directly and do not delegate to program administrators and judges the critical decisions that have to be made on some difficult issues, especially the resource allocation issues. [13] The courts are working hard to help society to frame policies that accomodate competing interests arising from the use of modern medical technology, but they are increasingly asking for legislative help in drawing the line where collective interests shall prevail over an individual's undisputed needs.

Uncertainty Over Definitions and Roles

The third global observation about the current U.S. legal system is a function of the first two: when the courts find that citizens have not been given clear notice about what is and is not acceptable behavior, especially in civil cases, they tend to err on the side of the citizen's interpretation of what is reasonable conduct. This observation is particularly important in health law where the technical and legal jargon seems to have taken on a life of its own.

In recent years, common sense definitions have been changed to the point where consumers and regulators may have very different images in mind when they use the same word. Take the word "physician" for example. State licensing statutes and most consumers (and all dictionaries) define physician as an individual trained and licensed as a doctor of medicine (and osteopathy in state statutes). The Social Security Act and important quality assurance regulations such as Medicare's Conditions of Participation for Hospitals [14], on the other hand, include persons with both less and different credentials in the term "physician." Indeed, the definition of "physician" in Section 1861(r) of the Social Security Act runs 35 lines and includes dentists, podiatrists, optometrists and chiropractors in addition to doctors of medicine and osteopathy.

As suggested at the beginning of this paper, "peer review" is another key term. The cases presented here and an amalgam of dictionary definitions for the two words suggest that "peer review" involves surveillance and evaluation by persons who are equals, in health care persons who are professional equals.

This definition is very different from what many government and private agencies call peer review. Many of the Federal health insurance programs, for example, include non-clinical, insurance review activities under the rubric of "peer review" (e.g., eligibility, technology coverage, length of stay). While such insurance reviews may cover important issues of access and affordability, they may also have nothing to do with the quality of care actually being provided. More importantly, such uses of the term may cause misunderstandings with consumers and courts that could have been avoided with more common sense use of language by legislators and regulators.

The remaining sections of this paper explore some of this confusion about definitions and functions. They examine important areas of law on professional and peer review and describe what can happen when neither consumers, nor providers, nor courts seem certain what conduct is permitted, i.e., when there is great uncertainty about the role that health care professionals may play in efforts to assess quality of care and to inform or protect consumer decision making. Some of the issues surrounding objective versus subject quality assessment criteria, consumer versus expert assessment perspectives, and individual versus societal interests are explored. The goal is to show that the judiciary (i.e., the courts) shares with the legislative and executive branches the tension that is caused by the rapid and fundamental changes being made in our health care systems.

STATE LICENSURE AND DISCIPLINE

State licensure and discipline are discussed briefly here for two reasons. First, though the number of individuals disciplined each year is small, the ultimate sanction available to licensing Boards (i.e., license revocation) can have a significant impact on the quality of patient care. As peer reviewers and licensing Boards and consumers become better versed in ways to attribute adverse outcomes to specific medical interventions, the number of sanctions and license revocations based on quality of care considerations should be expected to increase.

The second reason for describing the licensing and discipline of professionals is to show how assessment activities and quality standard-setting have moved out of the exclusive domain of physicians to be shared by other professionals and lay persons. [15] Because licensing is one of the older forms of professional regulation, it illustrates the transition from peer to peer-plus-lay review of professional conduct and decision making that is emerging in other areas of health law discussed here.

Two aspects of licensure involve peer review in quality assessment. First, standards for getting and for losing a license are supposed to depend on the preparation and conduct, respectively, of an individual health-care practitioner. Second, an institutional license (and sanctions available to institutional licensing agencies) is supposed to reflect the capabilities of an entire institution. Key requirements of institutional licensure in many states are: compliance with practitioner credentialing rules and fulfillment of patient care quality assessment and quality assurance measures set by accrediting bodies. In this sense, institutional licensure strongly reinforces the requirements for individual licensure. In most instances, state licensing statutes for individuals and institutions give impetus to--and must rely substantially on--voluntary profession-sponsored standards. [16] [17]

In each area of law discussed, it is important to note the overriding purpose of the public policy involved. In the case of state licensing statutes for both individuals and institutions, the legislative goal "is to safeguard the public from being mistreated or misled by incompetent or unscrupulous practitioners, rather than to protect the physicians [or institutions] themselves". [18]

State legislatures have pursued this consumer protection goal with two types of statutory requirement: prospective standards about who can practice medicine (or another health-care profession) and about what an institution has to do to qualify as a hospital or other health-care provider, and standards for making retrospective determinations about whether the conduct of an individual or institution warrants sanctions by a licensing body or private accreditation entity.

An illustration of problems that can arise in the prospective definition of license requirements is the recent situation surrounding licensing of U.S.-citizen foreign medical graduates (FMGs) and foreign national FMGs. This evolving public policy area is of interest here for three reasons. First, the standards for licensing, though set by state legislatures, defer substantially to recommendations from organized medicine. For example, the Liaison Committee on Medical Education, the Accreditation Council on Graduate Medical Education, and the Accrediation Council on Continuing Medical Education are all sponsored, funded, and staffed by large medical organizations like the American Medical Association.

The Educational Commission for Foreign Medical Graduates (ECFMG) is a separate entity that counsels and tests FMGs. It, too, is sponsored by the established organizations: the Association of American Medical Colleges, the American Board of Medical Specialties (ABMS), the American Hospital Association (AHA), the American Medical Association (AMA), the Association for Hospital Medical Education, the Federation of State Medical Boards (FSMB), and the National Medical Association. Not surprisingly, these organizations tend to control the policies embraced by these councils and committees.

Second, the mainstream U.S. medical community has raised questions about the qualifications of and quality of care provided by foreign-trained practitioners. Third, both U.S.-citizen and foreign-national FMGs are challenging some of the recent licensure requirements imposed on them on the grounds that they are not valid consumer protection provisions, but are barriers set up to protect established physicians' economic interests. [19] FMG licensing issues, like other health law issues discussed here, have mainstream medical professionals and their associations raising "quality of care" concerns while the opposition contends that these arguments are merely a smoke screen to cover these physicians' unwillingness to compete for patients or share the financial rewards of patient care. Policy challenges similar to those raised by the FMGs have also been raised by many independently licensed, non-physician practitioners. [20]

Retrospective disciplinary actions by a licensing Board, like prospective standard setting for licensure, can also present peer review problems. A look at Illinois' Medical Practice Act suggests why there are intra-profession, peer evaluation problems. Section 4433 of the Professions and Occupations Code lists 28 grounds for revoking or suspending a physician's license. Offenses 4, 5, 10, 16, 20, and 25 are set out below. Note how vague the statutory language is:

- gross or repeated malpractice resulting in serious injury or death of a patient;
- engaging in dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud or harm the public;
- holding one's self out to treat human ailments by making false statements, or by specifically designating any disease, or group of diseases and making false claim's of one's skill, or of the efficacy or value of one's medicine, treatment or remedy therefore;
- abandonment of a patient;
- immoral conduct in practice as a physician, or repeated acts of gross misconduct;

- professional incompetence as manifested by poor standards of care.

The Illinois State Medical Disciplinary Board consists of five physicians, two lay persons, one osteopath, and one chiropractor. These are the people who have to interpret and apply the disciplinary provisions set out above, with only nominal help from regulatory guidelines. These are the people who have to set the standards for permissible and impermissible conduct in their application of this broad legislative language. The amibiguity and breadth of the statutory language invite many individuals facing the loss of their professional livelihood to litigate the judgments made by their reviewers on the Board. [21] Despite the best efforts of these individuals and their state agency staff, they sometimes do not succeed in imposing licensing sanctions.

PROFESSIONAL AND HOSPITAL LIABILITY (MALPRACTICE) LAW

Peer Defined Standards

"Malpractice" law involves the accountability of professionals and professional organizations for damage that may result from their negligent acts. A negligent act can involve acts of commission such as leaving a surgical sponge inside a patient or acts of omission such as failing to advise a patient about a foreseeable risk of surgery.

For the purposes of this paper, professional liability or "malpractice" law is important for two reasons. First, malpractice law is the area where the courts probably have the most experience in adjudicating professional standards and peer review issues. All of the major elements of both prosecution and defense of a case hinge on expert peer opinion and testimony: the standard of care for a generalist or a specialist, expectations of such a practitioner in that or a similar community, proof of a respected minority opinion about what is appropriate care and, finally, judgments about whether the defendant did or did not depart from the standards of care deemed applicable in the case.

Malpractice law--for both individuals and institutions--is also important in a discussion of peer-based quality assessment because it illustrates a growing trend toward public and judicial policies that favor power-sharing between the professions and lay persons. [22] Peer standards about what is appropriate behavior and peer review of professional conduct still are central to malpractice inquiries, but the patient's perspective is more dominant in many of the more recent standards being adopted by the courts (e.g., about what constitutes adequate communication in informed consent disputes).

In this discussion of malpractice law, three types of professionals and several types of professional liability situations are discussed. The three types of professionals include individual practitioners, hospital leaders and insurance reviewers who control access to care. The situations that can give rise to litigation based on claims of negligence and that rely substantially on peer testimony about quality of care include the following:

- A patient sues a physician for medical malpractice, usually alleging negligence in performing a procedure, failure to diagnose a disease, or failure to obtain an informed consent. At trial, "to prevail in a malpractice case, the plaintiff must establish through expert [peer] testimony both the standard of care and the fact that the defendant's conduct did not measure up to that standard." [23]

- A patient sues a hospital or other health care institution for an injury caused by an employee of the institution. As with other employers, the institution may be liable for the negligence of its employees and agents.
- A patient sues a limited license practitioner for an injury caused by that practitioner. The grounds for recovery are usually limited to negligent performance of a procedure rather than failure to diagnose or failure to obtain an informed consent, as with physicians, because such practitioners usually are not permitted these responsibilities under their license.
- A patient sues a consulting physician and a hospital (or other institution) for an injury caused by an limited license practitioner who is not an employee of either the physician or the hospital, but who has hospital privileges and was involved in the plaintiff's care. Under a variety of legal theories, the physician and institution may be held liable for the acts of the independent, limited license practitioner.

- A patient sues a hospital (or other institution) for an injury arising from the negligence of a member of the medical staff.
- Finally, a patient sues an insurance reviewer for a payor and the payor for negligently failing to approve payment for care, resulting in an injury to the plaintiff. Presumably, this cause of action can arise only when a peer reviewer prospectively refuses to authorize medical service ordered by a patient's care givers.

The following discussion will highlight the more important aspects of each of these situations where peer standards and peer review are critical elements in assessing the care provided. Note how some time-honored precepts in malpractice law are giving way to new ideas and, on the other hand, how some established ideas of accountability may be extended to previously protected actors.

Any discussion of malpractice law should begin with a description of the legal theories of "duty" and "negligence":

> The whole theory of negligence presupposes some uniform standard of behavior. Yet the infinite variety of situations which may arise makes it impossible to fix definite rules in advance for all

> conceivable human conduct. The utmost that can be done is to devise something in the nature of a formula, the application of which in each particular case must be left to the jury, or to the court. The standard of conduct which the community demands must be an external and objective one, rather than the individual judgment, good or bad, of the particular actor; and it must be, so far as possible, the same for all persons, since the law can have no favorites. At the same time, it must make proper allowance for the risk apparent to the actor, for his capacity to meet it, and for the circumstances under which he must act.
>
> The courts have dealt with this very difficult problem by creating a fictitious person, who never existed on land or sea: the "reasonable man of ordinary prudence." [24]

For every day citizens, negligence is "a failure to do what the reasonable person would do 'under the same or similar circumstances.'" [25] For individuals with special knowledge, like physicians, there is a duty to use that "care which is reasonable in light of their superior learning and experience, and [to use] any special skills, knowledge or training they may personally have over and above what is normally possessed by persons in the field." [26]

Several collateral concepts from malpractice law condition this general statement about a physician's duty of care. First, as indicated above, specialists within medicine, or within any health-care discipline, may be held to a higher standard of care than generalists. Second, in most jurisdictions the medical expert sitting in judgment of the one charged must be (1) trained in the same area of medicine, and (2) from the same or a similar community so as to reflect an understanding of the expectations and resources in the defendant's community. This "locality rule" is frequently discarded where (1) the plaintiff can show that there is a widely understood national standard of care, or (2) where the defendant is a specialist and there is a presumption that this small group of specialists share common training, experience and knowledge (i.e., common national standards of care).

Another important, though often forgotten, qualifier is that the negligence "formula" described above only requires that "a doctor must have and use the knowledge, skill and care ordinarily possessed and employed by members of the profession in good standing . . .[and that] it is not the middle but the minimum common skill which is to be looked to". [27] Only when an individual holds himself out as a specialist, flatly misrepresents his credentials, or professes to have greater skill or training than he does is a court to hold him to a higher standard of care, i.e., the level of skill that he professed to have. Williams v. Piontkowski, for example, involved a chiropractor licensed to practice obstetrics but not to practice medicine. The court found that the chiropractor had intentionally misled his patient into believing that he was a regularly licensed medical practitioner and ruled, as a matter of law, that the practitioner should be held to the same standard of care as a fully licensed medical doctor. [28]

Typical cases involving physicians might include a family physician being held to a cardiologist's standards of skill and knowledge if the physician told patients that he was a heart specialist or a pediatrician being held to an obstetrician's standards if he took on the tasks of prenatal care and delivery for a teen-age patient.

One final legal caveat needs to be mentioned because it is increasingly important in disputes within the health-care professions and between outside reviewers and practitioners. Recognizing that there are areas where even the experts will disagree, malpractice law holds that "where there are different schools of medical thought, and alternative methods of acceptable treatment, . . .the dispute cannot be settled by the law, and the doctor is entitled to be judged according to the tenets of the school the doctor professes to follow". [29] Though there have been cases recently that seemed to legitimize some questionable practices (e.g., laetrile and other unproven therapies for cancer) when used by duly licensed physicians, the courts usually require some corroborating expert testimony that supports the appropriateness of the practice under review. [30] "A 'school' must be a recognized one with definite principles, and it must be the line of thought of a respectable minority of the profession". [31]

One trend away from profession-dictated standards is evident in the development of the law on informed consent. "Historically, the adequacy of physician communication in obtaining a patient's consent was judged by asking what a 'reasonable physician' would disclose to a patient given the expected risks and benefits. Most courts now have rejected this standard in favor of one that asks what a 'reasonable patient' in the plaintiff's position would expect to be told. Some courts have gone farther in promoting patient autonomy and adopted an 'individual patient' standard . . .that requires a physician to analyze each individual's values, idiosyncracies and preferences" in determining what to disclose and how to obtain a truly informed consent. [32]

The simple fact that there are as many medical malpractice cases brought by plaintiffs--and lost--as there are suggests that many patients find profession-dictated standards unacceptable. Indeed, more and more physicians are losing cases that they might well have won a decade ago. In part this is because of the popular notion--hard to exclude from the consideration of judges and juries--that medicine should be as precise as its underlying science appears to be. The public has seen the progress in patient care that science can provide and has undervalued the message about the art and the risks that remain. [33]

Unfortunately, it is not only the lay public that may have an unrealistic view of medicine's capabilities. In a recent paper on "Quality of Care", Willis Goldbeck, Executive Director of the Washington Business Group on Health, called for national standards of medical practice. He wrote that "science does not vary by ZIP code and [that] the very concept of 'community standards of medicine' is a contradiction in terms." [34] It is somewhat surprising that such a prominent expert on community resources should call for national "quality" standards--which tend to be higher (and more costly) than local standards--when he knows the resource limitations in terms of both finances and providers that exist in so many communities.

As suggested earlier, it is important to look at the overriding purpose of an area of law in order to predict how it may evolve given new circumstances. With licensing laws, the unquestioned purpose is to protect consumers. In malpractice law, there are different goals. Clearly, the overall intent is to compensate individuals who have been injured by the negligence of a health-care practitioner or other provider. In setting the standards for determining when there is negligence, however, the professional community and the courts have tried to assure that adequate care and the exercise of "reasonable" clinical judgment will not be penalized even if there is a bad result that another practitioner might have avoided.

Malpractice law, like licensing laws, has also tried to be flexible in setting the standard of care where reasonable alternative treatments may be appropriate. [35] In a very real sense, then, the purpose of each state's case law and statutes on professional liability standards is to provide practitioners some general notice about what level of performance is expected by their peers and to see to it that persons outside a profession do not override that profession's standards of practice.

With this concern over control of practice standards in mind, it follows that among physicians, and between physicians and other health care practitioners, there is likely to be a fair amount of dispute over standard-setting. [36] For this reason, the courts have carefully delineated who is, and who is not, a peer for purposes of expert testimony at trial. Since each state has developed its own law and rules of procedure, there are differences among jurisdictions. However, the rules about who can qualify as an expert for purposes of professional liability litigation are fairly uniform. Several Illinois cases illustrate what can happen in these "quality of care" disputes.

Illustrative Cases

In Dolan v. Galluzzo (1979) and Botehlo v. Bycura (1984), the plaintiffs were suing podiatrists for malpractice (including failure to obtain an informed consent). In both cases, the plaintiff tried to bring in the expert testimony of an orthopedic specialist to establish the nature of the care that should have been given--the standard of care--and the departure from that standard that caused the injury to the plaintiff. In each case, the defendant podiatrist asked the court to exclude all testimony by "physicians and surgeons."

> The circuit court . . .ordered the plaintiff not to present 'the testimony of any physician and surgeon for the purpose of proving' the standard of care a podiatrist owes a patient, or for the purpose of demonstrating that the failure of the defendant to inform the plaintiff `of the reasonable [sic] foreseeable risks of the procedure . . .was or was not consistent with the standard of care owed by a podiatrist to a patient.'
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> Because the State has 'long recognized podiatrists as a separate and distinct profession of healers who are severely limited in their practice and whose educational requirements are substantially different than those of physicians,' and because 'the treatments utilized by the podiatric profession . . .are substantially different from those utilized by physicians and ortheopedic surgeons', . . .the defendant has the right to have his competence judged by the standards of his own distinct profession and not by those of any other. [37]

Plaintiffs in both cases argued that it was not good public policy to limit non-physician practitioners to review only by their profession because this could adversely affect the quality of care provided to patients. They argued that "the podiatric standard of care may be lower than that which should be owed [and that] the testimony of a physician would help establish that." The defendants countered that the plaintiffs voluntarily consulted the defendants and that they are, therefore, "presumed to elect that the treatment shall be according to the system or school of medicine to which such practitioner belongs" [38] and that they "cannot afterward complain that care received fell short of standards in another profession." [39]

The rationale offered by the court for its holding is important in appreciating the role of state government in setting quality of care standards by establishing standards for professional competency:

> Illinois statutes provide for the regulation of practitioners of medicine and surgery, physical therapy, nursing, pharmacy . . .etc. This is a clear expression by the legislature of public policy to recognize and regulate various schools of medicine. * * * We simply are not disposed to provide for what, in effect, may result in a higher standard of care when the legislature, by recognizing various schools of medicine, has not done so. To do so would not only be unfair to podiatrists . . .but it would also assume that science and medicine have achieved a universal standard of treatment of disease or injury. Such is not the case. In its wisdom, the legislature has recognized a fundamental tenet of contemporary life: no one person, group or school has yet succeeded in abstracting a universal medical method from the many changing methods used in science and medicine. [40]

Note the interplay between licensure and professional liability ideas in the court's reasoning. It is an open question whether the state legislature would have agreed with this assessment of its legislative intent in these cases. Indeed, it is precisely this sort of "judicial logic" and this type of explicit message from a court that can signal a state legislature that it is time to step in if it does not like the law that the court is making. And state legislators are stepping in to change some of the malpractice rules.

There is widespread interest in legislation that spells out precisely how a fair balance is to be struck by the courts in disputes between patients and their care providers. However, though many aspects of state common law and statutory law on malpractice are being changed by legislation, so far the fundamental principle that only professional equals should sit in judgment of their peers has not changed.

Contractual Limits on Malpractice

One piece of consumer protection legislation in the malpractice area that has been enacted by many states is the prohibition against practitioners seeking general releases from liability as a condition of providing services. Illinois Revised Statutes Section 4475, for example, states that "Releases from liability as [sic] condition of medical treatment is against public policy. Any contract or agreement signed by any person prior to or as a condition of such person receiving medical treatment in any form, which releases from liability any physician, hospital or other health care provider for any malfeasance, misfeasance, or nonfeasance in the course of administering any medical treatment or service is void and against the public policy of the State of Illinois."

Though private parties usually have the right to contractually arrange--or avoid--certain obligations in a relationship, the state has stepped in and declared that any private agreement that purports to release a health care practitioner from liability will not be enforced by the courts. This policy has been applied even in cases where the consumer, as well as the provider, has enjoyed a significant benefit (e.g., fee reduction) under the arrangement. [41]

It is important that such blanket releases from liability be distinguished from the concept of a plaintiff's common law contract remedy for malpractice. That concept, simply stated, is that any practitioner foolhardy enough to "contract to cure" an individual or to "warrant that there would be no untold [sic] results from [a procedure]" will be accountable for breach of contract if things go awry. [42] Needless to say, very few of these cases are filed by attorneys because they have learned that the courts place a substantial burden of proof on the plaintiff who claims there was such a contract.

Hospital Obligations to Assess Quality of Care

In hospitals, profession-generated standards and peer review also play a central role in quality assessment activities. Are the standards for quality assessment in hospitals and other health care institutions the same as those for practitioners in a malpractice action? Yes and no. For purposes of this paper, the most important discussion of hospital liability relates to the supervising of professional employees and the granting and supervision of privileges given independent practitioners, particularly the members of the medical staff.

A hospital's obligation to supervise practitioners and assure that high quality care is being provided arises from both common law (tort and contract) ideas and from statutory requirements. [43] Liability can arise from the decisions or acts of physician _employees_ as well as others, licensed and unlicensed, who are engaged in patient care. Liability for patients injured by the negligence of _non-employee_ practitioners also has been imposed on hospitals in many jurisdictions on the grounds that the institution has an obligation to assure the competence of those to whom it extends privileges.

"Hospitals owe a duty to patients to insure the competence of the medical staff through careful selection and review." [44]

There is a saying that bad cases make bad law, but in some situations bad cases make good law by providing legal remedies to an injured party that may prevent such injuries in the future. Darling v. Charleston Community Memorial Hospital [45] was such a landmark case in hospital negligence law. Darling involved a teen-age football player who had to have a leg amputated because of gangrene caused by a cast that was made too small to accomodate the boy's broken leg. The hospital was held liable for failure to review the attending physician's work and for the failure of its nurses to respond properly to signs of gangrene developing in the plaintiff's limb. Of particular interest here is the fact that the hospital's standard of care was created by the court in large part by reference to (1) state regulations for hospital licensure, (2) voluntary standards for hospital accreditation, and (3) the hospital's own by-laws. Again, the court used standards set for differing purposes to build a new standard of care for a hospital provider.

Even in cases where there is no contractual relationship between an institution and a patient, the institution may be held liable for patient welfare. In Riverside v. Loma Linda University, for example, a California appellate court ruled that the "university could be held liable for the negligence of two obstetrical residents in the university's residency program for care rendered to a patient in the county hospital [because] the university could 'reasonably foresee' that the failure to provide appropriate training and instruction to the residents might result in harm to patients in the county hospital treated by the residents, and there were no policy implications precluding the imposition of liability" (emphasis added). [46]

This last statement is important to understanding how health-care malpractice law is evolving. With health-care practitioners, there continue to be substantial policy considerations on the practitioners' side that offset the call by consumers for more strict standards of care (or more flexible grounds for recovery by plaintiffs). [47] In the past, public sentiment and judicial custom provided hospitals legal defenses or immunities available to "public service" and charitable institutions that are no longer accepted by the courts because of changed public and professional expectations. [48]

As the "business" aspects of hospital care become more pronounced, hospitals and other similar providers are finding themselves more and more vulnerable to innovative theories for plaintiff recoveries. The place of hospitals in the community is changing and as the "corporatization" of health care progresses, hospital counsel are finding themselves unable to raise significant public policy arguments as to why they should not be subject to "product" liability accountability as any other insurable business is.

Reference to Cases

In 1984, the California Medical Association (CMA) published What Physicians Should Know About Peer Review Liability. [49] This publication addresses only California law, but it is worthwhile reading because California tends to be the most progressive, consumer-oriented state. California is frequently the testing ground for law that may or may not be embraced by the rest of the country, but is worth considering.

The CMA publication includes excellent descriptions of most avenues of liability for peer review done by health-care practitioners and institutions, including proctoring, utilization review, prospective coverage reviews, innovative medical procedures, activities of bioethics committees, acts of allied health professionals, and the unauthorized practice of medicine. All of these activities can have quality of care implications, but only the potential liability of insurance reviewers will be covered in some detail here.

Liability for Insurance Reviews

State Run Health Benefits Programs

The question of liability for third party, prospective insurance reviews was raised in the case of *Wickline v. State of California* in July 1986. [50] The *Wickline* case is particularly important because it appears to be the first case to raise the possibility of liability for state payers and their agents. Both the facts and the court's statements are compelling.

Lois Wickline, the plaintiff, is a married woman in her mid-40's. She was being treated in Van Nuys Community Hospital by her family physician and two specialists in vascular disease and surgery. Her complaint was pain in her back and legs, and the diagnosis was arteriosclerotic occlusion of the abdominal aorta necessitating surgery to open the artery with a graft. California's medical assistance program, Medi-Cal, requires prospective approval for all such treatment. It agreed with the surgical plan and approved a 10 day hospitalization.

Because of post-surgical complications, Wickline required two additional surgeries the day after her initial "very major surgery" and a third surgical procedure for pain relief 6 days after the first surgery. Because of her "stormy" recovery period, the plaintiff's physicians requested 8 more days of hospitalization from Medi-Cal. The nurse-reviewer took the request to a randomly selected Medi-Cal physician consultant. On the basis of a phone call with the nurse-reviewer and without reviewing Wickline's diagnosis, significant history, clinical status or treatment plan as provided on the request for extension form, this physician approved a 4 day extension.

In discussions held shortly before this extension was to expire, Wickline's three physicians testified that they agreed that she needed to remain in the hospital if they were "going to be able to save both of [her] legs."

However, when the 4 day extension was up, none of them attempted to get such an extension from Medi-Cal. Each testified that they felt sure that it would not be approved.

Wickline was discharged from the hospital, suffered serious complications, and was readmitted 9 days later for treatment of a life-threatening infection that required amputation of her right leg, first below the knee and then, after 9 days, above the knee. At trial, her surgical specialist testified that if she had remained in the hospital for the period originally requested of Medi-Cal, she would not have suffered the loss of her leg.

Wickline sued the state on the grounds that a third party payor, in this case Medi-Cal, has "legal responsibility for harm caused to a patient when a cost containment program is applied in a manner which is alleged to have affected the implementation of the treating physician's medical judgment." Even though the court ruled that it could not reach this argument because the treating physicians had failed to request the time they thought the plaintiff needed, it went to extraordinary lengths to suggest what it believed should happen in such cases.

Despite the well established common law doctrine (and usual statutory provisions) that make a sovereign state immune from liability for the acts of its agents and employees [51], the court stated that in life-critical situations where health-care is concerned, the state and its agents should not enjoy unqualified immunity.

> The patient who requires treatment and who is harmed when care which should have been provided is not provided should recover for the injuries suffered from all those responsible for the deprivation of such care, including, when appropriate, health care payors. Third party payors of health care services can be held legally accountable when medically inappropriate decisions result from defects in the design or implementation of cost containment mechanisms . . .

[The message to physicians and other providers was equally clear]:

> . . .the physician who complies without protest with the limitations imposed by a third party payor, when his medical jdugment dictates otherwise, cannot avoid his ultimate responsibility for his patient's care. . .Medi-Cal did not override the medical judgment of Wickline's treating physicians at the time of her discharge. It was given no opportunity to do so. Therefore, there can be no viable cause of action against it for the consequences of that discharge decision.
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> The court appreciates that what is at issue here is the effect of cost containment programs upon the professional judgment of physicians to prescribe hospital treatment for patients requiring the same. While we recognize, realistically, that cost

> consciousness has become a permanent feature of the health care system, it is essential that cost limitation programs not be permitted to corrupt medical judgment. [52]

On July 30, 1987, the California Supreme Court refused to hear the appeal in Wickline. This means that the decision of the appellate court can now be cited as the highest judicial authority in cases argued in California's lower trial courts. In theory, and usually in effect, lower courts are bound to apply the rules laid down in higher court decisions. Cases like Wickline also serve as important precedents for courts in other jurisdictions that are facing the same issues for the first time.

Indeed, Wickline is important less for the outcome--the state won--than for the court's ancillary warning: the state might not win under different circumstances. The Wickline court indicated that it might fashion a way to hold state agents accountable for their health care payment decisions, notwithstanding the state's immunity statutes, when negligence in decision making could have a direct and substantial adverse impact on a beneficiary.

Private and public sector peer review entities and their professional staff are waiting to see how the Wickline decision plays in that jurisdiction and elsewhere. The American Medical Association, on the other hand, is not waiting for court action. The AMA has drafted a model state bill "to impose liability and financial responsibility for injuries to patients consequent to review decisions by third-party payors." [53] Should the courts and state legislatures agree with the Wickline court's reasoning and the AMA model bill, state run health-care programs may face the substantial challenge of describing and defending what they believe to be an appropriate "standard of care" for insurers' case managers and utilization reviewers.

Medicare Reviews

Will this new accountability for insurance reviewers extend to participants in the Medicare program? Probably not, at least not in the near term. Congress has specifically shielded participants in the Federal peer review process (42 U.S.C. Sec.1320(c)). However, questions do remain: (1) how broad is the circle of protected participants, and (2) will the immunity conferred by statute be construed by the courts to be absolute or qualified immunity? A third question that may arise as a result of the Wickline case is, "What type of insurance review decision will enjoy immunity--a prospective one that can have substantial patient care consequences or only retrospective payment denials and physician sanctions?"

In a February 1987 case decided in the Eighth Circuit Court of Appeals, Kwoun v. Southeast Missouri Professional Standards Review Organization, [54] some early answers to these questions were provided. In Kwoun, three potential classes of defendants were granted absolute immunity from constitutional and common law claims associated with the Medicare peer review process. The three classes of defendants found immune from liability for their actions are (1) Federal employees, (2) private sector peer review contractors (deemed Federal "consultants") and their agents, and (3) state officials associated with the activity.

The Kwoun case involves a physician who HCFA tried to exclude from participation in Medicare for ten years, who was suspended from participation in the Missouri Medicaid program, and was subjected to proceedings to revoke his license as a result of a Medicare investigation. The peer review group's sanction recommendation to HCFA was based on the finding that Dr. Kwoun had provided services substantially in excess of those needed and had failed to meet professional standards of care (as required by 42 U.S.C. Sec. 1395y(d)(1)(c).

When an Administrative Law Judge ruled that HCFA and the peer review contractors had made "procedural and substantive errors" and reinstated Dr. Kwoun in the Medicare program, the physician sued the Federal program administrators, the peer review contractor and its individual reviewers, and the state licensing Board officials. He sued for (1) deprivation of Constitutionally protected property rights without due process, (2) malicious prosecution, and (3) deprivation of equal rights under the law to make and enforce contracts. In sum, his suit included both Constitutional and tort law claims.

The trial and appellate courts agreed that each class of defendant enjoys unqualified immunity from both the tort and Constitutional claims. The reasons for this immunity varied depending on which type of defendant was being considered. State law in Missouri made the licensing Board and its members immune from the tort claim for malicious prosecution. Federal law embodied in the peer review statute and as developed in prior case law supported the finding that these defendants were absolutely immune from tort claims because each was "acting within the outer perimeter of their line of duty" to promote the "quality of services . . .for which Medicare payment may be made." [55]

Though Federal executive officials usually enjoy only qualified immunity from Constitutional claims, the court found that the Medicare peer review and sanctions process is essentially a "prosecutorial" function and participants should, therefore, enjoy unqualified immunity from Constitutional claims. The rationale for shielding "prosecutorial" functions performed by Executive branch personnel is that any opportunity for retaliatory lawsuits would have a chilling effect on government agents fulfilling their prosecutorial duties. The court held that this immunity extends not only to the Federal employees, but also to the peer review "consultants" to the Department who handled Dr. Kwoun's investigation and recommended sanctions.

Finally, in addition to the statutory rationale for immunity already discussed, the court reasoned that the peer review activities involved in the Medicare program are sufficiently analogous to voluntary, private sector peer review and disciplinary committees that protection similar to that accorded such committees by state law should be given to peer reviewers in Federal programs barring any clear statutory directive to the contrary. [56]

Unlike the courts that reviewed Lois Wickline's case, the Kwoun courts did not have to decide whether public officials should somehow be accountable for their decisions (i.e., face potential liability) where they have prospective control over a patient's access to care. Kwoun involved only restrospective sanctions against a provider and presented few problems for the reviewing courts in terms of adverse effects on patients. If the errors made by HCFA and the peer reviewers had had direct patient care implications as in Wickline or had had even an indirect adverse impact on patient care (e.g., if Dr. Kwoun had been the only physician available to Medicare and Medicaid patients in a large geographical area), then the Kwoun courts might have been less inclined to confer unqualified immunity on the defendants.

Indeed, the Kwoun case was not unanimously decided and a well-reasoned dissenting opinion was published. The dissent states that the Medicare statute and legislative history support only a finding of qualified immunity for the Federal defendants and peer review contractors, the qualificiation being that these individuals are obligated to "exercise due care" in their decision making. As cases come forward that involve direct and substantial adverse effects for patients, it is entirely possible that the legal analysis and conclusion presented in the dissent will become the majority opinion among the courts. [57]

However, until cases arise that permit further judicial definition of the immunity issues, the Kwoun case provides a clear indication of how the courts are likely to view Federal peer review "malpractice" or negligence cases:

> We are not unmindful of the problems that may arise from the extension to medical peer review groups of absolute immunity from both common-law tort claims and constitutional claims. We are convinced, however, that in order for the Medicare program to work effectively, efficiently, and economically, see 42 U.S.C. Sec. 1395y(g), some controls on quality of care must be exercised. We are also convinced that the exercise of controls on quality of care greatly increases the benefits derived from the Medicare program by both the individual Medicare patients and our society as a whole. We are further convinced that the only way to ensure both the effectiveness of the peer review system and the willingness of private doctors to participate in it is to insulate them from damage claims that may result from that work. The alternative to the use of private doctors to review medical decisions is the use of agency officials, who are much less likely to possess the expertise to evaluate such medical decisions. The use of agency officials to review medical decisions would almost certainly lead to a far less effective, efficient, and economical Medicare program. In

> short, we are convinced that absolute immunity is "essential for the conduct of the public business" in this critical health care area. [58]

Private Sector Insurance Reviews

Standards for private sector insurance reviewers (i.e., health benefits managers or third-party administrators for a self-insured coporation) also remain to be set by the courts. Since private sector reviewers cannot share their governmental counterparts' immunities, there will undoubtedly be greater accountability for their acts. And, in all likelihood, the courts will consider quality assessment measures employed in governmental programs (e.g., PRO, QRO and Medicaid) in evaluating or setting standards for private sector entities.

Summary: Insurance Reviewers Liability

At the very least, it appears that established principles from traditional malpractice law will play a substantial role in setting the new standards of practice for both public and private sector insurance reviewers. These principles suggest that payors and program administrators who decide to have non-peer (e.g., nurse) and non-specialist physician reviewers interpose their judgments in physician-patient clinical decision making can anticipate much more litigation when there is a bad outcome. Only time will tell precisely how the established malpractice rules (especially those about who will participate in setting the new standards of practice) will be extended to this new class of health-care professionals with important patient care duties: the full and part-time insurance reviewers.

ANTITRUST LAW

Antitrust considerations are increasingly important in professional standard setting and peer review activities of all sorts. Because the antitrust laws are very complex and the individual cases equally complex, only the issues related to professional assessment of quality of care will be discussed here. Four situations are of particular interest:

- standard setting and enforcement of standards of practice set by a voluntary professional society for its members;
- standard setting and the enforcement of standards (i.e., ethical canons) regarding interaction of a professional society's members with another health care profession;
- formal "technology assessment" conducted by non-practitioners of a technique, i.e., peer review by non-subsrcibing peers; and

- liability exposure of hospitals and practitioners as a result of accreditation and credentialing processes.

Each of these situations involves health care professionals and their organizations in quality review activities that have the unequivocal intent to promote or restrain certain technologies and practices. As a result, each type of review runs the risk of exposing practitioners to liability for violation of antitrust laws that prohibit (1) "every contract, combination . . . and conspiracy in restraint of trade or commerce," and (2) "monopolization and attempts or conspiracies to monopolize" specific technologies or markets. [59]

Some acts are so clearly violations of these prohibitions (e.g., price fixing and group boycotts) that they are deemed per se violations, that is conduct for which no justification or explanation by a defendant will be permitted. In other cases, a "rule of reason" standard is used by a judge or jury to weigh the pro- and anti-competitive effects of an alleged restraint and determine whether the conduct is "unreasonable." Most health care antitrust cases have been tried under the "rule of reason" standard.

For the purposes of this paper, there are two central issues of concern in the developing law of health care antitrust. First, the courts are not in agreement as to whether (or when) quality of care concerns may justify an indisputable restraint on health care practices. This leads not only to problems of adjudication, but also leaves practitioners and their professional organizations without clear guidance as to what is and what is not acceptable behavior in regulating their own members and in offering public comment on professional practices. All of the problems that arise from lack of "notice" and the chilling effects due to uncertainty about the rules that were described in the opening section of this paper are evident in the antitrust cases.

The second issue prominent in the antitrust cases is the policy tension that arises when two activities that are clearly in the public interest require different and sometimes competing rules. In this case, the policy tension is that between promoting candid peer review by shielding the process and reviewers from public scrutiny, which means keeping the records out of antitrust trials, and promoting competition and informed consumer choice by permitting peer review records to be publicly disclosed or used for unintended (i.e., antitrust) purposes. [60] Indeed, it is the courts' attempts to balance these competing interests that has led to the different interpretations of the antitrust laws and the resulting uncertainty about what conduct is permissible.

The antitrust area more than any other discussed here illustrates what can happen when the courts are asked to go beyond their limits of adjudication and make policy. The application of the antitrust laws in each of the situations described above needs further clarification by Congress, particularly on the question as to whether quality of care justifications for anti-competitive restraints of trade are ever appropriate.

In one sense, the current but relatively quiet crisis in health care antitrust law is much more serious than the widely reported crisis in malpractice law. It is more serious because the policy problems are new, the cases can have sweeping effects, and the problem-solving that has marked malpractice developments for several decades is just beginning in the antitrust area. This newness heightens the uncertainty both in the courts and in the professions about where the policy balances will be struck. Antitrust problem-solving now is particularly important because failure to provide some guidance to the courts and practitioners rather soon could prove very costly.

The costs arise from two sources. First, there are the direct costs; antitrust cases are among the most expensive to litigate and can result in defendants having to pay all of a plaintiff's expenses plus treble damages where a violation is found. Perhaps the greater cost is more indirect, but even more ominous given the current interest in cost containment: antitrust suits brought by private parties can literally foreclose formal technology assessment that can promote informed consumer choice and insurer oversight of the marketplace. [61] In addition, the public may pay a substantial price, in terms of both personal safety and economic harm, if the antitrust laws are applied to limit consumer protection measures initiated by the professions, including professional efforts to fight quackery and set standards for competent, ethical behavior.

Some historical background on the application of the antitrust laws to health care is essential to show how arduous it may be for Congress, state legislatures, and the courts to strike an effective balance between the two competing and equally desirable public policy goals:

promoting economic competition among providers versus assuring that the professions can maintain their voluntary quality assessment programs and assist consumers in making informed choices among health care alternatives. This review of the developing case law will move from describing the general philosophy of health care antitrust policy to recent cases that bear directly on peer standard-setting and peer review activities that involve quality of care considerations.

Application of Antitrust Laws to the Professions

The first application of antitrust law to a state regulated profession came in 1975 in Goldfarb v. Virginia State Bar Association. The case involved a minimum fee schedule published by the Virginia State Bar Association in 1962 that was intended to keep the state's lawyers from "committing economic suicide as a profession." [62] As one author has noted, "If an association of automobile mechanics had adopted a minimum fee schedule similar to the one at issue in Goldfarb--for example, covering alignments, oil changes, tune-ups, and so forth--there would have been no question that the schedule would have been a per se violation of the antitrust laws". [63] The Court agreed and held that, henceforth, the "learned professions" would no longer be "categorically exempt from the general laws of competition governing the American marketplace". [64]

In a footnote in Goldfarb, however, the Court qualified its holding with language that has been much quoted in health care antitrust cases:

> The fact that a restraint [of trade] operates upon a profession as distinguished from a business is, of course, relevant in determining whether that particular restraint violates the Sherman Act. It would be unrealistic to view the practice of professions as interchangeable with other business activities, and automatically to apply to the professions antitrust concepts which originated in other areas. The public service aspect may require that a particular practice, which could properly be viewed as a violation of the Sherman Act in another context, be treated differently (emphasis added). [65]

In another landmark case in 1978, this time involving professional engineers, the Court was confronted with the argument that a profession should be permitted to limit competition when that competition might jeopardize public safety or health. The court rejected the public safety argument and decided that the "central principle of antitrust analysis [remains] the restraint's impact on competitive conditions". [66] The Court refused to accept the contention of the National Society of Professional Engineers that "the practice of awarding engineering contracts to the lowest bidder, regardless of quality, would be dangerous to the public health, safety and welfare" [67] and stated that "the Sherman Act reflects a legislative judgment that ultimately competition will produce not only lower prices, but also better goods and services". [68]

The message for health care providers from the cases lost by the lawyers and engineers was clear:

> . . .(1) the Supreme Court believes that application of the antitrust laws to the professions . . .will produce salutary effects, in terms of both the quality and the cost of professional services to consumers; and (2) doctors, hospitals, and others involved in health care cannot justify restraints on competition by invoking a 'public interest,' but are held to the same rigorous standards as other economic entities; these standards . . .require competitive justifications for other restraints (emphasis in original). [69]

Most of the health-care antitrust cases that followed Goldfarb in the late 1970's involved clearly economic policy disputes, such as fee schedules and bargaining arrangements between payors and providers. Some of the early cases and more of the recent cases, however, involve actions undertaken to restrain practices thought to be unproven or harmful to patients. These cases are included here because they involve challenges to peer standards from within a profession or challenges to the practice standards of one health-care profession by another. In other words, they affect the exercise of peer review and profession-generated restraints undertaken in the interests of patient care.

It is important to remember that antitrust actions such as those described here can be brought by one of three parties, depending on the circumstances: the Federal government (usually the Federal Trade Commission and the Department of Justice) when enforcement is under Federal law, the state Attorney General when enforcement is under state antitrust laws, or a private citizen, sometimes referred to as a "private Attorney General". As the discussion of individual cases shows, the circumstances of the plaintiff can have a substantial bearing on the extent to which the public's interests are considered in these trials.

Enforcement of Voluntary Standards

Antitrust lawsuits aimed at limiting enforcement of voluntary standards established by professional organizations have been brought by both state and Federal Attorneys General and by private parties. At least in theory, one would expect lawsuits brought by governmental entities to reflect careful consideration of competing public interests before the decision is made to challenge voluntary programs intended to promote high quality care. On the other hand, prevailing interpretations of antitrust law may force prosecutors to sue even when they believe the voluntary program provides a valuable public service.

Private parties, however, are not constrained by a weighing of larger social interests in their decision to sue under the antitrust laws. Therefore, voluntary standards organizations have to consider the perspective of both governmental and private entities when they set standards of conduct and attempt to enforce them. For the most part, the cases that follow suggest that it is the suits brought by private parties that present the greatest potential threat to voluntary peer review.

Koefoot v. American College of Surgeons is a good illustration of what can happen to a professional association when it attempts to enforce rules of practice that, at least on their face, are intended to ensure high quality patient care. [70] Koefoot involves a challenge to the "itinerant surgery rule" of the American College of Surgeons by a Fellow of the College who was expelled for violating the rule.

The facts in the case are simple and undisputed. Dr. Koefoot is a surgeon who travels around rural Nebraska performing surgery. Pre- and post-operative care is delegated to local, non-surgeon physicians. The College's "itinerant surgery rule" permits delegations of such care, but only to another surgeon. Therefore, Dr. Koefoot's pattern of practice violates the College's rule. The physician sued on the grounds that the rule violates the antitrust laws and that his expulsion from the College for violating the rule had adversely affected his practice and damaged his professional reputation.

Several family practice physicians (with financial support from the American Academy of Family Physicians) joined Dr. Koefoot as plaintiffs in the antitrust challenge to the rule against delegation of care. They joined the lawsuit because of their opposition to the notion that family physicians are not competent to provide care that may be entrusted to them by a surgeon. The family physicians (and the remaining hospital plaintiffs) joined in Dr. Koefoot's argument that the College's rule is motivated by economic, not quality of care, concerns. As such, they argued, the rule represents an unlawful restraint of their practice activities and an attempt to monopolize surgical care.

The Koefoot participants argued pre-trial motions in Federal District Court from 1984 until the trial in March 1987. Because rulings on pre-trial motions frequently have a substantial bearing on how an antitrust case is tried, the rulings in Koefoot that involved "quality of care" issues will be reviewed here. This is the court's own (January 14, 1987) statement of the issues of interest:

> . . .[T]he two centerpiece issues are: first, whether this action is to be tried under the per se rule, the rule of reason, or a combination of the two, and second, whether the legality of the itinerant surgery rule may be allowed to turn "on whether it was adopted for the purpose of improving patient care." [71]

The court decided that the case would be tried under a rule of reason analysis. It held that such a standard "is appropriate when facially legitimate ethical canons are challenged under the Sherman Act . . .facially legitimate ethical canons being rules of professional practice which, on their face, establish professional standards of care without reference to the economic interests of the professionals." [72] The court proceeded to describe how the parties should prepare for trial given its ruling.

Citing Wilk v. American Medical Association, a case decided earlier in the same Circuit Court that is described later in this section [73], the judge described permissible and impermissible defenses for the College's rule and disciplinary actions. Though the central question in "rule of reason" antitrust cases is whether the restraint in question has unreasonable anti-competitive effects, the judge ruled that some inquiry into what motivated the defendant to act could bear on the reasonableness of the conduct and should be permitted. Motivation could turn on: (1) a belief that the College's members would make more money if they limited referrals only to surgeons; (2) a belief that the College thought it was performing a public service in applying economic pressure to diminish or eliminate the general threat posed by itinerant surgery to public health, safety, and welfare; or (3) a belief that because pre- and post-operative care by non-surgeons presents a risk to the "health and lives of their patients", the College must forbid such practices.

The judge in Koefoot summarized these defenses as (1) the money motive, (2) the public interest motive, and (3) the patient care motive. [74] In the Wilk case, the appellate court had approved only the "patient care motive" as grounds for a defense under a rule of reason standard.

Having limited the purposes for which "quality of care" evidence could be introduced at trial by ACS, the court restated the longstanding balancing test envisioned by the "rule of reason" approach to such disputes:

> The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition . . .[t]o determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectional regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences [in terms of pro- and anti-competitive effects] (emphasis added). [75]

The court, therefore, indicated its intent to permit "harm" evidence to be raised by the College in the Koefoot trial only to the extent that it went to prove what motivated the College to establish the ethical canon about itinerant surgery. The court made it quite clear that ACS could not "seek to defend the itinerant surgery rule itself by attempting to prove that Dr. Koefoot's method of surgical care results in poorer patient outcomes . . .and [that ACS could not] seek to justify the ouster of Dr. Koefoot from the College by attacking the quality of his care". [76]

In ruling on these important pretrial motions, the court decided to severely limit the College's use of "harm" evidence because "the putative probative value [of quality of care evidence from Dr. Koefoot's practice was] substantially outweighed by the danger of unfair prejudice to the plaintiffs, confusion of the issues, and misleading the Jury." [77] The court emphasized that "[t]he quality of the care the plaintiffs' provide to their patients is not an ultimate issue in this case, either for the plaintiffs or the defendants. The ultimate issue in this case is the competitive effect of the defendants' conduct. [78] . . .As the Supreme Court has noted, the fact that consumers may be lead 'to make unwise and even dangerous choices' is not a defense to an antitrust challenge." [79]

Even though the College won the first round of litigation, with a March 5, 1987 jury decision that it had not violated the antitrust laws, the developing case law on enforcement of voluntary standards remains unsettling to practitioners and their professional organizations. The cases are moving more and more closely toward a rule that any profession-generated standard of conduct and subsequent enforcement of that standard that is anti-competitive in effect simply cannot be justified by the peer group's concerns about quality of care. Furthermore, these cases indicate that programs that consumers may view as "seal of approval" programs or quality indicators are to be regulated first and foremost as "economic," not "public health," initiatives.

There is an ironic postscript to the discussion of the Koefoot case that illustrates just how confused and confusing the legal standards are in this area of private standard-setting and disciplinary action by peer groups. In Greene v. Bowen, a Medicare sanctions case pending in Federal District Court in California, the physician-reviewer for the California Peer Review Organization (PRO) and the Inspector General for the Department of Health and Human Services have moved to sanction Dr. Greene, a surgeon, for failure to meet the ACS's itinerant surgery standard. Even as the medical plaintiffs are attacking the ACS rule in Koefoot as an ethical sham to cover surgeons' economic interests, the Federal government (DHHS) is invoking the rule as a quality of care standard under PRO regulations. The reverse is more typically the case, with the Federal Trade Commission or state Attorneys General arguing against the enforceability of restrictive ethical canons under antitrust law while providers try to raise quality of care justifications. [80]

Indeed, the facts in Dr. Greene's case are strikingly similar to those in Dr. Koefoot's case:

> . . .the Secretary's only challenge to Dr. Greene's care involved his postoperative care (his reliance on the patient's personal physician to provide the primary post-operative care while limiting his involvement to round-the-clock availability by phone, and personal visits immediately upon request or every two to three days as a matter of course).
>
> * * *
>
> . . .there was no explanation [by the Secretary] as to why Dr. Greene's alleged malfeasance rose to the level of a "gross and flagrant" violation. Indeed, in each report, the reviewer concluded simply: "The quality of this patient's care does not meet professionally recognized standards of care [i.e., the ACS "itinerant surgery rule"]." [81]

For the record, a "gross and flagrant" violation under the PRO regulations is "a violation of an obligation [which] has occurred in one or more instances [and] which presents an imminent danger to the health, safety, or well-being of the Medicare beneficiary or places the beneficiary unnecessarily in high risk situations" (42 U.S.C. Sec. 474.0(b)).

Review of Another Profession's Practices

The second of the four antitrust situations to be discussed here involves professional standards of practice that may have an impact on the interaction of a group's members with members of another health care profession. This type of situation is important because any limits placed on one profession's ability to scrutinize another's practices can, in turn, have an impact on the quality of care information that is available to consumers. Wilk v. the American Medical Association illustrates the enormous uncertainty, the lack of "notice" to professionals, that marks the current environment for such inter-profession review. Wilk involves a lawsuit brought by five chiropractors against the AMA and more than a dozen other defendants including the American Hospital Association, the American College of Surgeons, the American College of Physicians (ACP), the American College of Radiology (ACR), the American Academy of Orthopaedic Surgeons (AAOS), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO; formerly Joint Commission on Accreditation of Hospitals, JCAH).

The case was filed in 1976, decided in favor of the defendants by a jury, reversed in 1983 by a Federal appellate court with instructions to hold a new trial, retried before a Federal judge in May of this year, decided in favor of plaintiffs (against three of the defendants) in August, and is again on appeal. [82] Wilk is important not only because it illustrates the uncertainty that permeates health-care antitrust doctrine, but also because it illustrates how individual (as opposed to governmental) plaintiffs can use the law to make a legal end run around scientific evaluation that may better inform both practitioner and consumer choice. The case is but one of many "chiropractic" cases against major medical and hospital groups alleging that the they violated the Sherman Act from the 1960's to the present time by "combining to eliminate the chiropractic profession through their refusal to deal professionally with chiropractors". [83]

The Wilk case is also important because the rules laid down in the case will determine the role of quality of care evidence in future health care restraint of trade cases. These rules will pertain to peer evaluation and critical comment within a profession as well as between professions.

In the Wilk case, the chiropractors have charged that a "group boycott" spearheaded in the early 1960's by the AMA's Committee on Quackery (pursuant to one of the Association's ethical canons) involved defendants' "agreeing to induce individual medical doctors to forego any form of professional, research, or educational association with chiropractors, to induce hospital and other health care facilities to deny access to chiropractors, and to induce actual and prospective patients of chiropractors to avoid seeking chiropractic services". [84]

At the original trial in 1976, there was voluminous testimony about the alleged evils of chiropractic because of the trial court's ruling that it was germane to proving that "the boycott was the product of a genuine belief by medical doctors that chiropractic is dangerous quackery". [85] However, the appellate court ruled that the trial court's handling of this "prejudicial" evidence was inappropriate:

> During the pretrial stages and the trial, the able and experienced district judge suffered from the uncertainty which marks the law of boycotts by professionals: specifically, what legal justification, if any, exists for such boycotts when their effect is to restrain competition. . . On the eve of the trial, he embraced plaintiffs' contention that it was irrelevant whether defendants' conduct had been undertaken in the interest of public health, safety and welfare (the "public interest defense") . . . [86]

Nonetheless, the original trial became a "free-for-all" between medicine and the chiropractors about the merits of chiropractic practice: "[the appellate court] concluded that plaintiffs were prejudiced by the volume and nature of the evidence which defendants were permitted to present, impugning the validity of chiropractic and the integrity of chiropractors". [87]

In its decision, the appellate court also viewed with disapproval the following instructions to the jury:

> If you find from the evidence that defendants engaged in activities . . .which have had a substantial effect in preventing chiropractors from offering services which are reasonably interchangeable by consumers for the same purposes as the services offered by medical doctors, that would be an element weighing on the side of unreasonableness. If, on the other hand, you find from the evidence that defendants' activities did not have any substantial effect in preventing chiropractors from offering such services as licensure permits, that would be an element weighing on the side of the reasonableness of the defendants' activities.
>
> * * *
>
> In this regard, it is a proper function of professional associations to formulate and express principles concerning desirable standards of professional conduct and service . . . such principles may benefit the public by raising professional standards generally, and by helping to insure that the profession merits the trust that the public necessarily places in its members.
>
> In judging whether a particular professional standard in operation produces an unreasonable restraint of trade, it is necessary to consider the genuineness of the justification advanced in support of the standard itself, the manner of its enforcement, and the effects of it on the relevant area of trade or commerce.
>
> * * *

> . . .The question of whether chiropractic poses an impermissible hazard to the health and welfare of the public is one for the Congress and/or the state legislatures to resolve, not the defendants or other private persons or groups. Because those legislative entities alone have the authority to determine whether chiropractors should be permitted to offer their services to the general public, the law will not allow their decision to be overturned.
>
> It is a different question, however, whether members of the medical profession may limit their own relationships with chiropractors for the purpose of practicing their own profession according to standards they consider necessary or desirable for the proper practice of medicine. [88]

The appellate court stated: "Plainly the instructions [to the jury] as given failed to convey that the single standard is whether the challenged agreement is one that promotes competition or one that suppresses competition. . . .[I]t is [the] effect or consequence which controls, not intent or motive. * * * [A] rule of reason test [is] geared simply, clearly and exclusively to the question whether the challenged conduct promoted or suppressed competition between medical doctors and chiropractors" (emphasis added). [89]

Nonetheless, the appellate court did hold that it could be appropriate "to modify the rule of reason test in a case involving a certain kind of question of ethics for the medical profession," [90] citing the special considerations footnote in Goldfarb:

> If it should be determined eventually in this case that the Sherman Act was violated, that determination should not rest on insistence that the Act is indifferent to, or even hostile to, the value of permitting medical doctors to honor in their practice what they perceive to be scientific method, or indifferent to or hostile to the value of encouragement, from within the profession, to its members to honor scientific method by declining to associate with those thought to dishonor it. _A value independent of the values attributed to unrestrained competition must enter the equation. The reasonableness of any resulting restraint on competition must be determined by a reconciliation of values of different kinds_. [Nonetheless,] because Congress has for so long assigned such pronounced value to freedom of competition and the Supreme Court has for so long applied the rule of reason _so as virtually to exclude other values_, . . .the adaptation of the rule of reason [to cases that involve a professional association's ethical principles] . . .should impose a heavy burden on those who would justify conduct having significant anticompetitive effects (emphasis added). [91]

After the appellate decision in _Wilk_ and before the retrial began earlier this year, the U.S. Supreme Court reported its decision in a major case bearing on quality of care defenses available to antitrust defendants. The case of the _Federal Trade Commission v. Indiana Federation of Dentists_ [92] involved a group of Indiana dentists who were sued by the Federal Trade Commission for refusing to cooperate with insurers by providing x-rays for use in evaluating patients' claims for benefits. The dentists' defense was based on quality of care concerns; they did offer to let insurance reviewers examine the patient and review the patient record with each dentist to permit judgments to be made about needed care, but did not want simply to submit patient x-rays to insurers on the grounds that this provided an inadequate look at the total clinical situation.

The Supreme Court ruled that patients "and their insurers" are the dentists' "customers" [93], and held that the dental Federation's policy was a "horizontal agreement . . .to withhold from customers a particular service that they desire. [Such] a refusal to compete with respect to the package of services offered to customers, no less than a refusal to compete with respect to the price term of an agreement, impairs the ability of the market to advance social welfare by ensuring the provision of desired goods and services to consumers." [94]

The Court rejected the dentists' "noncompetitive 'quality of care' justifications" for their conduct with the following statement:

> The argument is, in essence, that an unrestrained market in which consumers are given access to the information they believe to be relevant to their choices will lead them to make unwise and even dangerous choices. Such an argument amounts to "nothing less than a frontal assault on the basic policy of the Sherman Act." Moreover, there is no particular reason to believe

that the provision of information will be more harmful to consumers in the market for dental services than in other markets . . . . [95]

(In a footnote to this part of its opinion, the Court offered a comment on the reliability of practitioner versus insurer judgments that may play a central role in the adjudication of future cases about who decides what constitutes "good" care: "There is little basis for concluding that, where such a divergence of professional judgment exists [provider versus insurer], the treatment recommendation made by the patient's dentist should be assumed to be the one that in fact represents the best interests of the patient.") [96]

The dentists' case is important because it seems to rule out all noncompetitive "quality of care" justifications for conduct of health-care providers' that may limit information or services available to consumers and their representatives. An early indication of how acceptable such a rule would be to the lower courts is included in the judge's recent decision on retrial of the AMA's chiropractic case (Wilk).

During the retrial, the plaintiff chiropractors did introduce the new argument that the Supreme Court's decision in the dentists' case should rule out the "patient care" defense approved by the appellate court in the original Wilk case. Though the judge hearing the Wilk retrial acceded to many of the plaintiffs arguments on other points, she rejected this argument on the grounds that "[t]he Supreme Court did not address the specific issue of whether a patient care defense on the facts in this case would be allowed," and decided to allow the "patient care" defense to be raised (emphasis added). [97]

The judge's statement on this point is noted because it indicates a reluctance to move these antitrust cases totally away from quality of care considerations. The judge clearly communicated her unhappiness with the Supreme Court's "non-competitive 'quality of care' justification" rule in the way she phrased her decision, i.e., she signalled her intent not to follow the ruling by "distinguishing the facts" of her case from the precedent-setting one. It will be interesting to see whether other trial and intermediate appellate courts will similarly decline to apply the rule laid down by the Supreme Court in the dentists' case. If they do, it is likely that the Supreme Court will agree to hear another case that presents these issues and offers an opportunity to change or clarify its view of the law in this sensitive area.

A brief further look at the Wilk retrial and decision is important to show how little consistency there is in these cases. First, it is noteworthy that the plaintiffs dropped their complaint for money damages before the retrial which permitted a bench trial instead of a jury trial. (When the case was first tried, it was decided in favor of the defendant medical groups by a jury.) On retrial, the only question that remained to be litigated was whether antitrust violations had occurred and were continuing to occur, thereby necessitating injunctive relief on plaintiffs' behalf.

The evidence on retrial showed that the defendants had abandoned the specific ethical canons about relationships with "non-scientific" practitioners complained of by the chiropractors. Nonetheless, because of evidence of continuing economic harm to chiropractors allegedly resulting from the decade-long "boycott", evidence for example that chiropractors earned less in 1984 than podiatrists and optometrists, the judge ruled that injunctive relief would be appropriate. The court indicated that some affirmative statement from the defendants (AMA, ACS, and ACR) to the effect that certain relationships with chiropractors are no longer considered unethical would be considered as part of the injunctive relief granted.

As of October 1987, ACS and ACR were still negotiating what kind of statement and publication might be made. The American Medical Association had decided to appeal the judge's decision.

Though she ruled in favor of the chiropractors, the judge on the Wilk retrial seemed to understand why these plaintiffs have spent such substantial time and money pursuing non-monetary relief in this case. "The plaintiffs clearly . . .want a judicial pronouncement that chiropractic is a valid, efficacious, even scientific health care service. I believe that the answer to that question can only be provided by a well designed, controlled, scientific study . . . I decline to pronounce chiropractic valid or invalid on anecdotal evidence." [98]

Nonetheless, the plaintiffs may be able to garner the imprimatur of approval that they seek with the affirmative statement that the "boycott" is over that has been ordered by the judge. An example of such a statement is that of the Illinois State Medical Society, a defendant in the litigation until it reached a separate agreement with the plaintiffs:

> There are and should be no ethical or collective impediments to full professional association and cooperation between doctors of chiropractic and medical physicians, except as provided by law.

Should the chiropractors succeed in compelling the publication of similar statements by these prominent medical defendants, all of the judge's reservations about chiropractic practice will disappear. Her refusal to endorse chiropractic as a scientific discipline and her acceptance of the legitimacy of medicine's "patient care" motivation will not be widely published for public consumption. What the general public will hear is the chiropractors' own interpretation of statements such as the one above and the more expansive one recently published by the American Hospital Association (Appendix A: "Statement of the American Hospital Association with Respect to the Profession of Chiropractic and Hospitals") that would suggest to the average consumer that chiropractic is now a well established, widely respected patient care discipline.

Private Antitrust Suits Against Technology Assessors

Chiropractic's goals in their antitrust cases (i.e., to compel public statements from mainstream practitioners that attest to their professional legitimacy) bear a striking resemblance to the goals sought by some physicians in disputes with their peers about the safety and efficacy of medical procedures. These suits represent the third (i.e. "technology assessment") type of antitrust situation to be considered here. The first case, Vest v. Waring [99], and the pending case of Schachar v. American Academy of Ophthalmology (AAO) [100] allege that the NIH-sponsored five year study of the safety and efficacy of radial keratotomy surgery resulted from a conspiracy by the AAO and a group of academic physicians "aimed at shutting private practitioners out of a potentially lucrative area of medicine." [101] In addition, the physician plaintiffs charged that these academic physicians were attempting to unlawfully "monopolize" this area of surgical practice.

Forced to settle the case during the lengthy pre-trial motion stage because of mounting expenses, the defendants found the plaintiffs demand for money damages rather modest ($250,000). What the plaintiffs really wanted from the defendants was a "statement intended to set forth certain current and historical facts about the radial keratotomy procedure [including among other things] that enough information is now available to establish that radial keratotomy is not an experimental procedure" with the "effect of encouraging insurance companies and other third-party payors to reimburse for the radial keratotomy procedure" (emphasis added). [102]

In Vest, the plaintiffs got the "seal of approval" they desired from the eminent defendant ophthalmologists because the defendants simply could not afford to defend the antitrust suit. This is perhaps the single most important aspect of antitrust exposure for health-care practitioners and institutions--and the single least understood consideration by legislators judging by the statements made and steps not taken with enactment of the Health Care Quality Improvement Act of 1986. Most individuals and institutions simply cannot afford to defend an antitrust case. Koefoot plaintiffs have reportedly spent more than $600,000 to date and the defendant ACS more than $1 million. Similarly, the AMA has spent almost $3 million and more than 11 years just on litigating the Wilk case. If the AMA ultimately loses the case, it will pay millions more in plaintiffs' legal fees.

Such suits against technology assessors should be expected to continue because the rewards for successful plaintiffs can be substantial and the antitrust laws do not put plaintiffs and defendants on an equal footing in the litigation. While winning plaintiffs can recover their legal fees from defendants, winning defendants have no similar hope of financial recovery. In addition, losing defendants can face money damages tripled by statutory directive. Though these provisions to encourage the average citizen to pursue redress against corporate giants may have been necessary when the antitrust laws were enacted sixty years ago, they may not be conducive to the development of health care antitrust policies that serve the public interest today.

The concern for persons interested in rigorous health care quality assessment is that, because of the costs, judicial settlements may be approved that do not reflect what might have happened if the case had been litigated to a conclusion on the merits. When a case is resolved by settlement in other types of disputes, even in other types of antitrust disputes, both the litigants and the public may be well served. With health care antitrust suits brought by private parties, however, there may be a strong public interest in the issues and outcome, but no one in court to assure that the public's interests are considered. A second concern is that potential exposure to such litigation even for good faith scientific inquiry (e.g., NIH funded research) has had a chilling effect on the willingness of experts to serve on review committees unless indemnity or immunity is assured. [103]

Unfortunately, this type of truncated judicial (versus scientific) resolution of "quality of care" issues seems an inevitable result in many cases if the antitrust laws are to be strictly applied to health-care providers. This will be especially true if quality of care justifications are impermissible or given very little weight by the courts.

The "technology assessment" cases, then, illustrate what can happen when peer evaluation impinges on the economic rewards sought by practitioners of new or controversial techniques. More of this kind of assault on "technology assessment" activities is bound to occur given the leverage that the antitrust laws provide to individual plaintiffs. Even the proponents of closer antitrust scrutiny of health-care providers have suggested that the courts need better instruction from the Congress and state legislatures about how to interpret the laws to protect innovators and legitimate competitors, but also to avoid being used by practitioners to advance practices that may not be safe and effective.

Again, a postscript should be added to the radial keratotomy story that shows how each of these areas of law can play off the others' activities and have an ultimate impact on consumer interests. According to one leading proponent of radial keratotomy surgery, the widespread publicity about the safety and efficacy issues raised in the antitrust litigation has led to an increase in malpractice lawsuits. [104] This suggests that consumers can and do use professional assessments offered in one legal forum to seek redress in another. The unfortunate aspect of consumer reliance on malpractice suits is that any remedy will come after the injury. (Though it can take a long time for malpractice litigation to cause the fundamental change in practice that is needed to prevent patient injury, improved patient care nonetheless remains one of the hoped for results of individual malpractice cases.) [105]

Institutional Peer Review Activities

The final type of antitrust situation that involves peer review in quality assessment programs--and affects consumer confidence in health care institutions--arises in the context of institutional accreditation and practitioner credentialing. Some of the antitrust issues arise in connection with defining the scope of practice of limited license practitioners, as in some of the chiropractic and podiatric cases. [106] [107] Of greater interest here are the cases that involve physician review of physician practices.

The problems that can arise in hospital-based peer review of practitioners with privileges is illustrated in the Patrick v. Burget case from Oregon. [108] Again, there are complicated antitrust issues being litigated in Patrick. However, it is fair to say that the main issues of interest here are whether Federal courts hearing antitrust cases should permit plaintiffs (1) to bring in evidence from peer review activities that is protected from public exposure by state statutes, and (2) to subject professionals to civil liability for their peer review activities.

Most states have provided statutory protection to proceedings of peer review entities and some, like Oregon, have extended immunity from civil liability to physicians who serve on medical peer review committees if they act in good faith. [109] In Patrick, the Federal court permitted the plaintiff to bring in evidence of his hospital's peer review committee's deliberations (reviews made after complaints about the quality of Patrick's care) and evidence provided by the committee to the state

Board of Medical Examiners that would not have been available to the plaintiff under state law if the action had been brought in state court. This evidence suggested that Dr. Patrick's reviewers, while legitimately concerned about the quality of care he was providing (a subject not disputed by plaintiff), also were unhappy with his aggressive surgical practices and his competition with surgeons in the town's clinic.

At the trial court level, the plaintiff won a substantial monetary award that, when trebled (to $2.1 million) according to antitrust law, could literally put the Astoria, Oregon clinic and the individual physician defendants into bankruptcy if it is not reversed on appeal. The trial court found that the evidence supported the view that the defendants had acted unlawfully to restrain the plaintiff's surgical trade.

On appeal, the Ninth Circuit Court of Appeals reversed the trial court. It held that physicians engaged in peer review are protected from Federal antitrust lawsuits under the "state action" doctrine. In essence, this doctrine states that where a state requires an activity and actively supervises that activity, the activity cannot be considered a restraint of trade under the Federal antitrust law. In this case, the activity involved is the licensure of hospitals (and supervision of state licensees) required by Oregon law.

Dr. Patrick has appealed the appellate court's decision to the U.S. Supreme Court which has agreed to rule on the case. In amici ("friend of the court") briefs filed by the AMA and others, the Court is being urged to recognize that "peer review promotes professional competence and is procompetitive activity that upholds the purpose of antitrust laws." [110] Amici have warned the Court that the courts will be "swamped with requests [by aggrieved practitioners] to evaluate their expertise and to determine hospital privileges for them" if it does not place limits on the "judicial surveillance" imposed on peer reviewers. [111]

The Supreme Court is sufficiently concerned about the Patrick case that it has asked the U.S. Solicitor General to file a brief in the case. The Solicitor General reportedly has urged the Court to reverse the decision of the appellate court finding that peer review is always protected by the state action doctrine. [112]

In all likelihood, the Supreme Court will reverse the Ninth Circuit's holding in Patrick and may go so far as to suggest a rule that, for example, would provide protection only to peer review that is truly "state action", i.e. that is actively, not passively, supervised by the state and that is done in "good faith". This compromise would seem to be in accord with the policy balance that the states have tried to achieve by statute and in accord with Congressional thinking as evidenced by provisions in the PRO law and by the peer review protections provided in the Health Care Quality Improvement Act of 1986.

Insurer Antitrust Exposure

One cannot leave a consideration of health care antitrust law without wondering what the private sector payors think about the evolving peer review antitrust rules. Surely most cannot be enamored of the idea that court decisions, not scientific inquiry (or legislative mandate), may determine what services are and are not to be considered "medically necessary." On the other hand, insurers may welcome more freewheeling competition among new and old providers and may agree with Willis Goldbeck's recent observation that, "Quality is the excuse for physician opposition to certified nurse midwives: [but] fear of loss of income is the reason". [113]

The opinion and activities of private payors are also germane because the payors may soon encounter their own antitrust challenges. They may find themselves named as defendants as a result of an apparent industry-wide decision not to cover a service (e.g., radial keratotomy) based on experts' assessments of the service. Such a case would give policy makers a clearer view of where the industry thinks the peer review antitrust policy balance should be struck--between peer restraints that may protect consumers and unfettered marketplace competition that may promote greater efficiency in health services.

STATE AND FEDERAL INITIATIVES

Like the rest of this paper, the description of state and Federal quality assessment initiatives will necessarily be illustrative, not exhaustive. In those instances where a new policy has elicited feedback, the feedback is described. Note that with both state and Federal legislation that has been enacted recently, there are policy ambiguities and conflicts. These may arise from either substantial flaws in legislative drafting or a failure to appreciate the existing tensions attending peer review activities. At the very least, the problems encountered suggest that Congress and the states may be moving too rapidly to pursue desired policy changes, thereby assisting no one--not consumers, practitioners, or hospitals--in their policy making.

On the Federal level, there has been a spate of activity related to "quality of care" recently. This is, perhaps, a natural follow-on to the cost containment systems legislated in 1983. Federal legislation has addressed two areas where quality assessment policy needed clarification: (1) private peer review protection under the Health Care Quality Improvement Act of 1986, and (2) expansion of Medicare quality assessment under provisions of the Omnibus Budget Reconciliation Act of 1986 (OBRA). [114]

Omnibus Budget Reconciliation Act

One of the key sections of OBRA calls for HCFA to extend peer review to HMOs and Competitive Medical Plans (CMPs). Such quality review activity is clearly a high priority of the Administration judging by comments on HCFA's plans sent by the Office of Management and Budget (OMB) to HCFA Administrator, William Roper, M.D.:

> PROs and the alternative quality review organizations (QROs) must quickly and reliably identify low quality health care providers, separating high quality providers from those with poor quality. PROs and QROs must concentrate their resources, greatly stepping up reviews, on poor quality providers. Once quality problems are identified, PROs and QROs must assure timely and effective corrective actions to rectify all quality problems. The

> PROs and QROs must continue more intensive reviews and sampling until the HMO is either terminated from Medicare or provides high quality care. [115]

How will quality reviewers under the new PRO and QRO programs fulfill the Administration's hopes? The answers should begin to come in very soon because the PRO/QRO contracts have been announced by HCFA and regulations give the contractors only 90-120 days to develop their quality assessment plans. However, there are clues available already about what Congress intends. Again and again in the new legislation and regulations, the reference point for measuring "quality" is "professionally recognized standards of health care." [116] A new twist to that requirement is that Federal programs must now be sure to exclude those providing incompetent or "substandard" care. [117] And in all of these judgments about what is standard or substandard care, the practicing physician is the central actor and organized peer review the central activity. (See Appendix B: "Expanding Role of Peer Review: PROs in Transition.")

Health Care Quality Improvement Act of 1986

What is Congress doing to assure that suitable non-governmental peer review can take place? Enactment of the Health Care Quality Improvement Act of 1986 suggests that Congress clearly is interested in enhancing voluntary quality assessment programs by protecting some private sector peer review activities (i.e., hospital peer review). [118] However, analysts have identified several questions surrounding the new law that will probably limit its effectiveness:

1. Does the Federal law preempt (i.e., overrule contrary provisions) of state statutes that shield peer review committee proceedings, records and participants? The General Counsel for the American Medical Association believes the law does not preempt state statutes, but the Association's Associate General Counsel, a seasoned health law expert, believes the law could be interpreted to do so. Other legal analysts have voiced the same concern which means that the question is probably a valid one. [119]

2. Existing state statutes may shield (1) review activities or (2) review entities that are not protected under the new Federal law. Are these provisions in state laws still enforceable?

3. The Federal law requires compliance with some broadly stated due process requirements or the reviewers' immunity may be forfeited. There are numerous questions about precisely what standards must be established to

assure procedural due process for those being reviewed. For example, "should an individual physician's right to immunity [for work on a peer review committee] depend upon factors over which that physician has no control, such as the [hospital's] subsequent compliance with all notice and due process or reporting obligations?" [120]

4. Will the peer review and disciplinary records collected by the Federal clearinghouse under the law be disclosable by HCFA to (a) members of the public or (b) parties to malpractice litigation? Congressman Waxman has reportedly indicated that such material is not to be disclosed, that it is shielded as it would be under most state statutes. HCFA officials have stated that such material is disclosable once litigation has commenced. [121]

These substantive questions about the implementation of the law have left peer review physicians and hospital administrators little more assured than they were before the law was passed. Thus, the early effects of the lawmaking are less than hoped for, i.e., liability exposure is still having a chilling effect on voluntary private sector peer review activities.

In addition to questions about how the law will be interpreted, there is one additional hurdle to implementation that remains--the national credentials and sanctions clearinghouse that is to be the hub of the law's enforcement has missed the opening date set by statute (November 15, 1987). Clearinghouse delays have reportedly been encountered for two reasons. First, the Justice Department has expressed serious antitrust concerns about HCFA contracting for management of the clearinghouse with any group that represents one of the professions covered by the law. [122] Second, funding requirements to support the clearinghouse activity varied considerably among the twenty organizations that submitted "letters of interest" about the contract to HCFA, and funds have not yet been cleared for implementing any clearinghouse contract. [123]

State Regulatory Initiatives

On the state level, one of the primary activities of interest is legislation being enacted to serve two purposes: (1) to provide practitioners some relief in the malpractice area, and (2) as a quid pro quo, to augment hospitals' risk management programs in order to promote quality assessment activities. Like the Federal initiative in the Health Care Quality Improvement Act, one key part of the risk management/quality review work at the state level may involve periodic mandatory recredentialing of practitioners. New York state, for example, "is studying the possibility of recredentialing the state's 43,000 physicians, probably by using the hospitals' existing peer review structures." [124]

Massachusetts was one of the first states to enact such malpractice reform legislation and has already received some "feedback," a lawsuit filed by prominent hospitals in the state.

The Massachusetts law is intended to "achieve a reduction or stabilization of the frequency, amount and cost of claims against physicians and licensed hospitals by enhancing the quality of patient care in the Commonwealth. This legislative goal is to be achieved, in part, by risk management programs conducted through medical peer review committees of each hospital." [125] After October 1, 1987, all hospitals were, as a condition of licensure, required to have risk management programs and to provide "major incident reports" to the state licensing Board.

The mainstay of the required risk management programs are "medical peer review committees . . .a committee of a medical staff . . .[whose functions include] the evaluation or improvement of the quality of health care . . .services, [and] the determination whether health care services were performed in compliance with the applicable standards of care . . ." [126]

One reason the Massachusetts hospitals have sued is because the law has conflicting provisions about the disclosure of reports of hospitals' peer review committees. Under the law, hospital peer review committee records are protected from public access and scrutiny, but "there is no statutory protection from civil discovery or evidentiary admissibility for any [state licensing] Board record." [127]

> The effect of the disparate statutory treatment of peer review committee records and Board records is to make Board records, in contrast to peer review committee records, (i) always subject to discovery under the Massachusetts Rules of Civil Procedure and never disqualified from admissibility in evidence, and (ii) always available for public inspection, except records obtained in a specific investigation, and then only during that investigation. [128]

The net result of the new law is that "comprehensive evaluation[s] of a [physician's] clinical skills, competence and judgment" required to be done and to be protected at the hospital level are, "once in the hands of the Board [pursuant to mandatory reporting], . . .available to the public through the Freedom of Information Act and civil discovery." [129]

If the Massachusetts' law turns out to be unintentionally contradictory, it can be fixed. However, it is possible that the legislators intended to give the public more access to "quality of care" information now available to state officials. Certainly, this is the usual and intended result of statutory programs that increase the private sector's accountability to public sector regulators, in this instance the state licensing Board for hospitals. However, if greater public accountability for quality is what Massachusetts' legislators seek and if steps are not taken to preclude disclosure of the details of medical staff peer review deliberations, what physician is going to agree to participate on these hospital committees?

When peer review is done behind closed doors and used within an institution to educate or discipline physicians, it can be highly effective in improving physician practices and patient care. That is why the activity is shielded from public scrutiny by state law. When public disclosure is threatened, however, the atmosphere of professional reform through education is shattered and persons outside the profession and the institution can use peer review records for punitive, not educational, purposes. State legislatures have decided that, on balance, any individuals' right to learn something more about what may have happened in a given case (i.e., in a malpractice or antitrust suit) are outweighed by the public's interest in improved patient care resulting from candid and confidential peer review.

Conclusions about State and Federal Initiatives

The problem for state and Federal agencies responsible for (1) setting standards of care for government-run programs, and (2) sending signals to consumers about "quality of care" is the same one that the courts have faced for years in malpractice litigation--the professional peer or peer group is the only one that can *credibly* assess and comment on a practitioner's patient care practices. Given that fact, a regulator has to "trust" the professions to do honest peer review. The *quid pro quo* from the professions' point of view is that legislators and regulators must give all good faith peer review protection from practitioners unhappy with the results of the peer review process. [130]

Federal law and regulations and most state's statutes purport to provide the desired protection.

But imagine what will happen to state-mandated quality assessment activities if the Patrick (antitrust) case from Oregon is reversed? And imagine the impact on state and Federal programs if the courts embrace the philosophy of public sector accountability suggested in Wickline and advocated by the AMA, thereby stripping away a government reviewer's immunity from liability for patient harm? Both of these events could happen very soon, bringing even more conflict to the nation's health-care quality assessment agenda.

CONCLUSION

Two trends are evident in the development of law related to professional and peer review in quality assessment programs:

1. Consumers and their advocates are increasingly competing with health care professionals for greater influence in determining what constitutes acceptable quality of care, particularly in terms of the perspective and elements to be considered. [131]

2. Health care professionals--from physicians to nurses to chiropractors--are competing with each other for greater influence in determining what constitutes acceptable patient care practices and outcomes. This

competition among the professions has been evident in the past in the politics of licensure and health care payment policy as more and more non-physician practitioners successfully petitioned to be independently licensed and to be reimbursed directly.

Such competition--this time for control of quality standards and assessment methods--should be expected to spill over into the quality assessment debates. The competition should become particularly keen as policy makers move toward conditioning payment for service on meeting certain yet to be defined quality of care indices. [131]

A third trend is also suggested in this paper: private sector groups and the courts are signalling Congress and the state legislatures that they need more guidance about what private sector actions to promote "quality of care" standard-setting and quality related discipline will be permitted. The cases reviewed suggest that the viability and efficiency of the courts could be markedly enhanced with such guidance. Even in those areas of law (e.g., the fundamentals of malpractice and antitrust) where Congress and the states may not wish to open the Pandora's box of statutory amendments, hearings could be held and legislative intent recorded to guide subsequent judicial deliberations.

Where should such debates begin? There are several policy questions related to the place of professional and peer review in quality assessment programs that merit prompt legislative attention:

- What is the proper balance between immunity and accountability for (a) public program agents and (b) private sector insurance reviewers who have the authority to control beneficiaries' access to care?
- What is the proper policy balance between private discipline protected from public disclosure and public disclosure about quality indicators that could inform consumer choices? Many subsidiary questions follow: As a practical matter, can private sector peer review be candid and effective if both the records and the conclusions are open to public scrutiny? What will happen if professionals cease to volunteer for hospital and ambulatory care peer review? Could mandatory private sector peer review (i.e., participation as a condition of maintaining a license to practice) be effective?

- Should the Health Care Quality Improvement Act of 1986 be clarified to respond to the problems of implementation raised by health law specialists?
- Should the Health Care Quality Improvement Act be expanded to shield more types of professional review and "technology assessment" (and the reviewers and assessors) when the participants are making good faith, voluntary efforts to contribute to the nation's health care quality assessment enterprises?
- Will PROs and Quality Review Organizations (QROs) serve as government's "medical police force," or will they be independent review bodies that emphasize physician, hospital and consumer education? [133]
- In the antitrust area, should quality of care considerations ever justify private parties' acts to restrain the practices of another health care profession or professional? If so, under what circumstances? If not, what are the appropriate roles of private

professional organizations in promoting quality assessment and educating members and consumers?

- What is the appropriate governmental role in promoting efficiency through health care competition, on the one hand, and promoting public health by protecting consumers from health fraud, on the other hand? If private professionals are to be limited in the ways that they can help consumers assess the safety, efficacy, and appropriateness of another professional's practices (for fear of antitrust or libel and slander suits), [134] and if the government is unavailable or ineffective in helping consumers to interpret claims being made, how will consumers make informed choices about health care alternatives?

This paper does not address the pros and cons of alternative answers to these policy questions. Depth of inquiry has been sacrificed for breadth of inquiry; problem description has preceeded problem solving. Congress and the state legislatures are the only authorities in a position to pursue these issues and look for prompt, efficient and unambiguous ways to resolve the controversies that may adversely be affecting health care quality assessment initiatives.

Since these initiatives are increasingly relying on professional standard-setting and peer review, problem solving in these policy areas seems an appropriate place to begin. The complexity of the issues demand that creative solutions be pursued in a spirit of conciliation. With this in mind, the recommendations of the U.S. Administrative Conference regarding regulatory consensus building in its "Procedures for Negotiating Proposed Regulations" [135] might merit Congressional attention as "quality of care" deliberations gain momentum.

One subject in particular offers a worthwhile starting point for such a negotiated regulatory policy: the facilitation by government of private sector, profession-generated anti-fraud or "truth in advertising" activities. A united effort to redirect to health care the $10 billion a year that is going to health fraud could send important signals to consumers about how to critically evaluate claims being made by all competing providers. [136] Such an exercise in public and private sector cooperation might also move the parties from the current adversarial mood to a collaborative frame of mind that could lead to improved problem solving and enhanced consumer education in other areas of health care quality assessment.

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    Sec. 820.2: Except as otherwise provided by statute, a public employee is not liable for an injury resulting from his act or omission where the act of omission was the result of the exercise of the discretion vested in him, whether or not such discretion be abused (emphasis added).

Sec. 818.4: A public entity *is not liable* for an injury caused by the issuance, denial, suspension or revocation of, or by the failure or refusal to issue, deny, suspend or revoke, any permit, license, certificate, approval, order, or similar authorization where the public entity or an employee ...is authorized by enactment to determine whether or not such authorization should be issued, denied, suspended or revoked (emphasis added to highlight language conferring absolute immunity).

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Though some of these practitioners are included in the term "physician" under the Social Security Act, there was sufficient concern about a hospital being "taken over" by limited license practitioners that the 1986 Medicare Conditions of Participation for Hospitals followed the JCAHO accreditation model and required that an Executive Committee of the medical staff be composed of fully licensed physicians. This requirement was imposed even though the revised conditions generally leave decisions about medical versus non-medical governance of hospital departments to the discretion of the institution (unlike the pre-1986 regulations). See, for example, "Medicare and Medicaid Programs; Conditions of Participation for Hospitals," Fed. Reg. 51 (116): 22010-22052, p. 22021, June 17, 1986.

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